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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,063	08/23/2001	Michael R. Dupelle	04644-101001	1672

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/938,063

Applicant(s)

DUPELLE ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 11-17, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gliner et al. (6,178,357) in view of Ferrari (5,571,165) and further in view of Smith Ind. Pub. Lim. Co., (EPO 434258 A2). Gliner et al. shows a defibrillator comprising a defibrillator control box; a pair of mechanically integrally connected electrode pads (20); leads (16) connecting the electrode pads to the defibrillator control box; each electrode pad comprises an electrode sized and configured for defibrillation; an adhesive area configured to adhere the defibrillation electrode to a patients skin, the adhesive area of each electrode pad being separated from the adhesive area of the other electrode by an area without adhesive (Col. 4, lines 32-36; Col. 5, lines 10-14; Col. 5, lines 59-65), and at least two electrode release sheets (42) one on each of the electrode pads (Col. 4, lines 1-36; Col. 5, lines 10-14; Col. 5, lines 59-65).

Although Gliner et al. fails to specifically point out that the electrode pads have a skin contacting area of at least 50 centimeters squared, attention is directed to Ferrari which teaches that the ANSI/AAMI (American National Standards Institute/ Association for the Advancement of Medical Instrumentation) specifies the minimum active area of individual self adhesive electrodes used for adult defibrillation should be at least 50 centimeters squared (Col. 1, lines 19-28). Therefore, it would have been obvious to one with ordinary skill in the art at the time the

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invention was made to size the defibrillation electrodes of Gliner et al. to have an active area of at least 50 square centimeters in order to comply with industry standards for the minimum active area of individual defibrillation electrodes.

Although Gliner et al. and Ferrari fail to show a first portion of the release sheet covering the adhesive and a second portion of the release sheet extending from the first portion and being folded so that the release sheet can be peeled away from the adhesive by pulling the second portion in a direction substantially parallel to the plane of the electrode pad while the electrode pad is held in a desired location, attention is directed to Smith Ind. Pub. Lim. Co., which shows an adhesive pad with a release sheet having this configuration (Figs. 1-4). Smith Ind. Pub. Lim. Co. teaches this release sheet configuration provides a means to avoid adhesive contact with the fingers so that the adhesive will not become contaminated or lose effectiveness (Col. 4, lines 29-32, Col. 1, lines 17-20, lines 24-33). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the electrode pad of Gliner et al. and Ferrari with a release sheet having the configuration of Smith Ind. Pub. Lim. Co. in order to avoid adhesive contact with the fingers so that the adhesive will not become contaminated and lose effectiveness.

With respect to claims 12, and 22, Gliner et al. shows the electrode pad further comprises a conductive gel associated with each electrode pad (32).

Regarding claims 13-14, and 23- 24, Gliner et al. shows a non-conductive adhesive surrounding the gel (Col. 4, lines 32-36).

With respect to claims 15, and 19, Smith Ind. Pub. Lim. Co. shows the release sheet is folded in a substantially U-shaped configuration (Figs. 1-4).

Regarding claim 17, Gliner et al. shows the defibrillator comprises an automatic external defibrillator.

Regarding claim 20, Smith Ind. Pub. Lim. Co. shows an edge of the second portion of the release sheet extends beyond an adjacent edge of the pad, providing a pull-tab (23, 33) that can be grasped during removal of the release sheet (Fig. 3).

With respect to claim 21, Smith Ind. Pub. Lim. Co. shows the release sheet is configured so that as the release sheet is peeled away, a fold about which the release sheet is folded travels in the direction in which the second portion is pulled (Fig. 3).

Response to Arguments

3. Applicant's arguments filed 11/5/04 have been fully considered but they are not persuasive.

In response to applicant's assertion that there is no reason for concern about a user's finger contacting the adhesive of a defibrillation electrode, the examiner disagrees. Finger contamination of electrodes can cause dirt and oils to become adhered to the adhesive and reduce its effectiveness. In fact, applicant mentions in the background of the invention that release sheets for electrodes are utilized to maintain the electrodes in a sanitary condition (page 1, lines 14-17).

In response to a applicant's argument that the applicant's electrode pad assembly does not suffer from the finger grasping problems of Smith Ind. because there is an area between the electrodes without adhesive, the examiner disagrees. Applicant asserts that the area without adhesive can be grasped without danger of contacting the adhesive. However, just because the area without adhesive can be grasped does not mean that in all instances it will be grasped. In

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certain situations, the adhesive portion of the electrode pad assembly could accidentally or unintentionally be grasped. In that case, the adhesive would become contaminated with dirt and oils from the fingers and cause the adhesive to lose effectiveness. In defibrillation electrodes the loss of effectiveness of the adhesive is not desirable. See applicant's specification at page 1, lines 18-29.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen (formerly Droesch) whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen

kdm

Angela D. Sykes

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